

Acute appendicitis
(artist's interpretation)

WARNING

Clindamycin therapy has been associated with severe colitis which may end fatally. Therefore, it should be reserved for serious infections where less toxic antimicrobial agents are inappropriate, as described in the Indications Section. It should not be used in patients with nonbacterial infections, such as most upper respiratory tract infections. Studies indicate a toxin(s) produced by Clostridia is one primary cause of antibiotic associated colitis. Cholestyramine and colestipol resins have been shown to bind the toxin *in vitro*. See WARNINGS section. The colitis is usually characterized by severe, persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus. Endoscopic examination may reveal pseudomembranous colitis.

When significant diarrhea occurs, the drug should be discontinued or, if necessary, continued only with close observation of the patient. Large bowel endoscopy has been recommended.

Antiperistaltic agents such as opiates and diphenoxylate with atropine (Lomotil) may prolong and/or worsen the condition. Vancomycin has been found to be effective in the treatment of antibiotic associated pseudomembranous colitis produced by *Clostridium difficile*. The usual adult dose is 500 milligrams to 2 grams of vancomycin orally per day in three to four divided doses administered for 7 to 10 days. Cholestyramine or colestipol resins bind vancomycin *in vitro*. If both a resin and vancomycin are to be administered concurrently, it may be advisable to separate the time of administration of each drug.

Diarrhea, colitis, and pseudomembranous colitis have been observed to begin up to several weeks following cessation of therapy with clindamycin.

INDICATIONS

Serious infections ...

CONTRAINDICATIONS

History of hypersensitivity to clindamycin or lincomycin.

WARNINGS

See WARNING box. A toxin produced by Clostridia is one primary cause of antibiotic associated colitis. Cholestyramine and colestipol resins have been shown to bind the toxin *in vitro*. Mild cases of colitis may respond to drug discontinuance alone. Moderate to severe cases should be managed promptly with fluid, electrolyte and protein supplementation as indicated. Vancomycin has been found to be effective in the treatment of antibiotic associated pseudomembranous colitis produced by *Clostridium difficile*. The usual adult dosage is 500 mg to 2 grams of vancomycin orally per day in 3 or 4 divided doses for 7 to 10 days. Systemic corticoids and corticoid retention enemas may help relieve the colitis. Other causes of colitis should also be considered.

A careful inquiry should be made concerning previous sensitivities to drugs and other allergens. Because antagonism has been demonstrated between clindamycin and erythromycin *in vitro*, these drugs should not be administered concurrently. *Usage in Pregnancy:* Safety has not been established. *Usage in Newborns and Infants:* Appropriate monitoring of organ system functions is desirable. *Nursing Mothers:* Clindamycin has been reported to appear in breast milk in ranges of 0.7 to 3.8 mcg/ml. *Usage in Meningitis:* Since clindamycin does not diffuse adequately into the cerebrospinal fluid, it should not be used to treat meningitis.

SERIOUS ANAPHYLACTOID REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE. OXYGEN AND INTRAVENOUS CORTICOSTEROIDS SHOULD ALSO BE ADMINISTERED AS INDICATED.

PRECAUTIONS

Older patients with associated severe illness may tolerate diarrhea less well. When clindamycin is indicated in these patients, they should be carefully monitored for change in bowel frequency. Prescribe with caution in individuals with a history of gastrointestinal disease, particularly colitis and agents. Use with caution in patients receiving such agents. Do not inject clindamycin IV undiluted as a bolus. Dilute prior to IV administration to 300 mg per 50 ml or more of diluent. Infuse over at least 10-60 minutes. CLEOCIN HCl Capsules contain FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals, especially in patients who also have aspirin hypersensitivity.

ADVERSE REACTIONS

Gastrointestinal: Abdominal pain, nausea, vomiting and diarrhea. (See WARNING box).

Hypersensitivity Reactions: Maculopapular rash and urticaria. Generalized mild to moderate morbilliform-like skin rashes are the most frequent adverse reactions. Rare instances of erythema multiforme, some resembling Stevens-Johnson syndrome, have been reported. A few cases of anaphylactoid reactions have been reported. If a hypersensitivity reaction occurs, the drug should be discontinued. The usual agents should be available for emergency treatment. *Liver:* Jaundice and abnormalities in liver function tests have been observed. *Hematopoietic:* Neutropenia, eosinophilia, agranulocytosis and thrombocytopenia have been reported; no direct etiologic relationship to concurrent clindamycin therapy has been made. *Local Reactions:* Pain, induration and sterile abscess have been reported after intramuscular injection and thrombophlebitis after intravenous infusion. Reactions can be minimized or avoided by giving deep intramuscular injections and avoiding prolonged use of indwelling intravenous catheters. *Musculoskeletal:* Rare instances of polyarthritis have been reported. *Cardiovascular:* Rare instances of cardiopulmonary arrest and hypotension have been reported following too rapid IV infusion.

HOW SUPPLIED

Available as sterile solution with each ml containing clindamycin phosphate equivalent to 150 mg clindamycin base. Ampoules of 2 and 4 ml.

CLEOCIN HCl as 75 mg and 150 mg capsules.

Caution: Federal law prohibits dispensing without prescription.

For additional product information see your Upjohn representative.